

**BelAm Study of Thyroid Cancer and Other Thyroid Diseases in Belarus
Following the Chornobyl Accident**

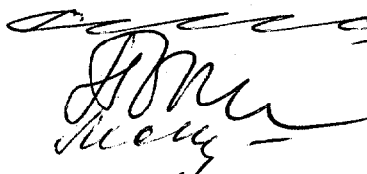
Progress Report for Quarter Beginning 01/10/2000 and Ending 31/12/2000

BelAm Director



V.A. Stezhko

**VICE-DIRECTOR ON SCIENCE
VICE-DIRECTOR ON CLINIC
SCREENING CENTER**

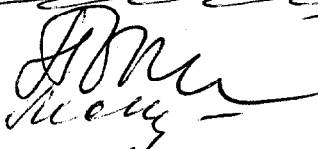


V.A. OSTAPENKO

QUALITY CONTROL GROUP

V.A. RZHEUTSKY

DATA COORDINATING CENTER

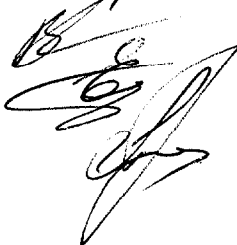


O.N. POLIANSKAJA

DOZIMETRY GROUP

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I. Executive Summary

For the reported quarter 12 meeting were conducted together with Project Unit leaders who reported of study progress.

A request for equipment, materials and supplies for 2001 has been prepared. The request has been submitted to Columbia University.

A set of documents necessary for ISTC partnership has been prepared and submitted to Moscow office of ISTC.

Data obtained for the period of Project activity were reviewed, reports reflecting progress of the study were prepared and presented at Tri-National meeting in the USA, November 2000.

Together with Columbia University, National Cancer Institute, Belarus Red Cross the procedure was worked out for arranging food baskets gifts for subjects coming to screening.

Administrative support was given to the screening process in Bragin, Rechitsa, Khoyniki, Narovlia raions. Three articles were published in local newspapers.

Some preliminary work has been performed for the training of Belarus specialists participating in the Project dedicated to the second screening cycle.

New working arias have been arranged for Project Units in Gomel Dispensary.

II. Report on Tasks

Task 1 Establish and implement a management plan and quality control procedures for the study

Progress on task:

QC Group

During the current quarter quality control group reviewed forms completed at Gomel and Minsk examining centers. In Minsk the forms were reviewed by Director Assistant on Quality Control, and in Gomel – by the Expert on Quality Control. Quality control of form completion was conducted in Epi Group, Dosimetry and Laboratory Groups.

By the results of review of Cytology form completed in Gomel, it was revealed unsatisfactory level of competence of specialist involved in the Project. That is why a decision was made for repeated review of slides and form completion by the cytologist in Minsk. For Gomel cytologist training course in Minsk examining was scheduled.

Together with DCC a software was created for automatic control of number of subject referred to FNA according to the new criteria. The software was tested during which it was revealed that patients with hypoechogenic nodules of less than 1 cm are not always referred to FNA. That is why additional training with endocrinologists was conducted where endocrinologists were explained new criteria for FNA referral. The efficiency of performed activity will be evaluated next quarter

A list of patients referred to hospitalization to the Center of Oncopatology and did not show up there was reviewed. To these patient repeated letters will be sent directly by oncologist.

Task 2 Select a sample of records from the dose files to establish study cohort

Milestone 2.3 Select the sample

By the end of the fourth quarter 10,392 subjects have been enrolled to the cohort.

Task 3 Trace subjects to determine current address

Milestone 3.2 Develop methods for tracing difficult-to-locate subjects

Progress on task:

Epi Group

Epi group made a file on 522 individuals who had moved to another places without any signs of new address. The file includes individuals born 1968-1979. Among this group for 148 persons there was incomplete information concerning new addresses. Locating of subjects was performed through address offices of different oblasts of Belarus. The result of searching activity was the following: 9 individuals moved to Brest oblast, 6 individuals moved to Vitebsk oblast, 6 individuals moved to Grodno oblast, 19- to Minsk oblast, 10 – to Mogilev oblast, 98 individuals moved to Gomel oblast.

404 individuals having moved from their former places of residence should be located by cross search through all address offices of the country. The lists are sent to the address offices of Minsk and Gomel oblasts.

Operational difficulties encountered in accomplishing the task:

Cross search through address offices of other oblasts could be possible in case of financial support.

Milestone 3.3 Trace subjects for current address

Progress on task:

Epi Group

During the reported quarter epidemiologists together with mobile team visited the following raions: Slavgorod, Chericov, Loev, Drybyn, Rechitsa, Bragin. It is a common procedure to send letters inviting to examination performed by mobile team to provisional cohort subjects with confirmed address but having no money to come to Minsk or who did not respond to letters. When epidemiologist comes in field he/she visited subjects' places for verification of address, explanation and invitation to the screening. As a result of such activity the addresses have been verified for 46 subjects living in Slavgorod and Chericov raions, 40 subjects in Loev raion, 35 – in Bragin raion, Besides, through local medical station the addresses of 60 subjects living in Drybyn raion, 83 subjects living in Rechitsa raion and 60 subject from Bragin raion have been verified.

Operational difficulties encountered in accomplishing the task:

Lack of transport for epidemiologists limits the possibility of visiting subjects' places.

Milestone 3.4 Trace subjects who did not respond to invitation for current address

Progress on task:

Epi Group

Verification of addresses was made at the time of mobile team activity as it is described in i.3.3..

Task 4 Enroll and maintain participation of subjects in the study

Operational difficulties encountered in accomplishing the task:

Epi Group

In the fourth quarter given activity was not performed because of lack of financial support.

Task 5 Conduct initial screening examination of subjects

Milestone 5.1 Develop data collection forms

Progress on task:

Data Coordinating Center

Hospitalization form (Acsacovschina) has been updated: in the section referral for further treatment several items have been added: referral to the National Oncopathology Center and date

of referral and referral to the Screening Center and the date of referral. To the hospitalization form (NTOPC) the following field has been added: subsequent referral to Acsacovschina, to NTOPC, to the Screening Center, dates of referral as well as refusal from referral.

Introduced fields will allow tracing the cohort subject from hospitalization to screening examination.

Milestone 5.2 Staff and equip fixed center and mobile screening teams

Operational difficulties encountered in accomplishing the task:

Administrative group

Portable ultrasound instruments required for mobile teams are still at customs house because the documents accompanying the shipment does not contain mark of humanity.

Central Laboratory

Because of unstable power supply in the Central Laboratory it is necessary to purchase 3 UPS: 2 – for computers and one for luminiscent counter (115 VA). Additional computer is required for acceleration of data entry. Additional refrigerator with freezer is required to store samples of serum and urine as well as reagents. Automatic pipettes are required – 4 pcs.

Milestone 5.4 Send invitation letters to schedule appointments for examination

Progress on task:

Data Coordinating Center

Epi Group

During the fourth quarter cohort subjects were examined in Minsk examining center, Gomel examining center and by mobile teams of Minsk center.

In accordance with the place of examination invitational letters to initial examination were sent to the subjects. Invitations were sent to the subjects newly located and to those who had statuses no response within a month, reserve, given preliminary consent but did not show up. Table 2 (Cycle 1) contains information of mailed letters.

Milestone 5.5 Conduct screening examinations

Progress on task:

Central Laboratory

In the forth quarter laboratory tests were performed for 1138 cohort subjects. Besides thyroid hormones and antibodies were estimated for 2179 subjects examined in 1997-1998. The total amount of work of the Central Laboratory in the 4-th quarter was 14,996 tests.

Screening Center

The number of examined in the 4-th quarter subjects was 972, and the total number of examined subjects since the very beginning was 10,392. Distribution of subjects according to the place of examination is presented in the Table 4. As it is evident the majority of subjects were examined by Minsk mobile team in field.

Completeness of subjects' examination is presented in Table 5. Cases of missing examination stations were very rare and totally were 1%.

Results of the screening according to the data preliminary endocrine summary are presented in Table 6.

Relative number of subjects without thyroid pathology was 64.26%. Percentage of subjects with thyroid pathology was 7.36%.

Verified number of patients having thyrotoxicosis without goiter was 44. In the previous report Table 9 did not reflect the number of patients with subclinical hyperthyroidism (i.2.5 and 2.5.4).

Milestone 5.6 Notify subjects of final screening results

Progress on task:

Data Coordinating Center

A draft of letter for notification of subjects of the results of laboratory tests and final endocrine summary was prepared. Some preliminary work has been done for notification of subjects (software has been worked out).

Operational difficulties encountered in accomplishing the task:

Data Coordinating Center

Because of lack of financial support there was no possibility to send the subjects results of laboratory blood test and final summaries of the screening. In future it is planned to send such notifications monthly.

Task 6 Conduct second screening of subjects

Milestone 6.1 Review screening process and data collection forms, and revise as necessary

Progress on task:

Data Coordinating Center

For the purpose of arranging for the second screening cycle the study forms were reviewed. Changes were introduced to the forms. Information concerning educational statuses of the subject and the parents was added to the Locator Form. In the Palpation Form size of thyroid was transformed in accordance with WHO classification. Majority of changes was introduced to the Medical Interview and to Final Summary and Recommendations. Blocks of questions were transferred from the Laboratory Form and Palpation Form to Medical Interview to avoid duplications in different forms. Some changes were introduced to the Control Form, Ultrasound Examination Form and laboratory forms. Therefore unified forms were worked out for the second screening cycle.

Central Laboratory

The Central Laboratory participated in updating of laboratory forms for the second screening cycle. Questions concerning consumption of iodine containing foods were transferred from the Urine Collection and Processing Form to the special questionnaire.

Information concerning geographical place of blood collection was taken from the Form of Blood Collection. Minor changes were introduced to the Form of Blood Test Results..

Milestone 6.3 Send invitation letters to schedule appointments for examination

Progress on task:

Data Coordinating Center

Epi Group

Subjects examined in 1997 and did not show up in 1998, 1999 and 2000 were invited to the repeated examination. This group included people who gave preliminary consent but did not show up, could not come for different reasons, and who did not respond. Monthly invitations were sent to recall examination for medical follow up in accordance with the date scheduled by the endocrinologist during screening examination.

Information of mailed letters is presented in the Table 2 (Cycle 2)

Milestone 6.4 Conduct screening examinations

Progress on task:

All in all 720 subjects were examined repeatedly, 23 of them – in the 4-th quarter. Nodular pathology was revealed in 89 subjects (5 of them in the 4-th quarter). 28 subjects had FNAs (2

subjects in the 4-th quarter). According to the data of cytological examination preliminary diagnosis of thyroid cancer was made to 3 patients, suspicious cancer – to 3 patients. By the results of pathomorphological examination the diagnosis was confirmed to 4 patients

Milestone 6.5 Notify subjects of final screening results

Operational difficulties encountered in accomplishing the task:

Data Coordinating Center

Because of the reasons indicated in the item 5.6 notifications of the screening findings in the 4-th quarter were not sent to subjects.

Task 7 Determine which subjects have developed thyroid cancer or other thyroid diseases

Milestone 7.2 Conduct FNA on appropriate subjects and refer appropriate subjects for surgery

Progress on task:

Screening Center

FNA was required for 137 subjects. 42.30% of them were aspirated. 24,1% were refused. Results of FNA according to the place of screening and cytology findings are presented in the Table 7.

A share of non-informative slides from the total number of aspirations was 24.7%

To estimate adequacy of cytology material in presence of patient procedure of express staining was launched.

Profound clinical examination in the Hospital of RCIRME (Acsacovschina) was done for 54 patients, 6 of them were referred to surgery (1 subject refused). Discrepancy in diagnoses was found in 12 subjects: in number of nodules – 6 cases, in main diagnosis (diffusive goiter and AIT) – 4 cases, in estimation of thyroid function – 2 cases.

Milestone 7.3 Provide final diagnosis after surgery

Progress on task:

Screening Center

8 subjects had surgeries on occasion of thyroid cancer (1 subject had repeated surgery), 2 subjects – on occasion of thyroid adenoma. Pathomorphological conclusion was received for 7 patients. One conclusion on subject having had repeated surgery is missed.

Milestone 7.5 Complete laboratory tests for subjects examined

Laboratory tests for examined subjects were performed in accordance with Operations Manual. When necessary and in accordance with endocrinology summary repeated laboratory tests were performed. Blood and urine samples are kept frozen for unlimited period of time. Endocrinologist is immediately informed of obtained findings.

Milestone 7.6 Complete final endocrine summary for each subject

Progress on task:

Screening Center

Final summary was completed for 6,211, including 165 subjects in the 4-th quarter. Distribution of patients considering their diagnoses is presented in the Table 9.

All, in all 53 subjects having thyroid cancer have been revealed, including 49 in the 1-st screening cycle and 4 in the second

Milestone 7.7 Conduct expert reviews of ultrasound findings

Progress on task:

QC Group

Ultrasound expert reviewed ultrasound images of all thyroid cancer cases, 100 nodular goiter cases and at random of the subjects without pathology. While identifying images several defects have been revealed.

Milestone 7.8 Conduct expert reviews of cytology for subjects who had FNA

Progress on task:

QC Group

Expert reviews of cytology were conducted by Dr. Greenbaum

Task 8 Develop data management system, and key enter data collected for the study

Milestone 8.1 Design computer data base to store data

Progress on task:

Data Coordinating Center

DCC group started developing software for invitation of cohort subjects for 2-nd screening cycle. It was considered that subjects younger 18 years of age at the time of the screening should be examined once a year and older subjects – once two years.

A work has been initiated for automatic generation of corrections log following routine reviews of the DB.

In accordance with changes introduced to the Hospitalization Form (Acsacovschina) and Hospitalization Form (NCTOP) software for data entry of these forms was updated.

In the end of the 4-th quarter it was planned to mail the results of screening examination and New Year greetings to the cohort subjects. Software has been developed for mailing the results of screening on a regular base. Possibility was implemented for tracing final diagnosis at screening, results of laboratory blood tests, and notification of the results for a specified visit for any subject.

Milestone 8.2 Develop coding manual and data documentation

Progress on task:

Data Coordinating Center

In the fourth quarter further development of coding manual was continued. The structure of data for all epidemiology forms, screening forms, forms of hospitalization stage, forms of biopsy, cytology and pathomorphology. Unique codes have been added for missed values and not applicable values.

Milestone 8.3 Key enter information from data collection forms

Progress on task:

Data Coordinating Center

Key enter information from data collection forms was made in all the Project Units. Data collected in Minsk screening center and in field by mobile team were entered by operators of this center. Laboratory data from the Central Laboratory and were entered in the Central Laboratory. DCC personnel transferred data from the Project Units to DCC once a week. Data collected in Gomel screening center was key entered to the DB in DCC. Forms of FNA, cytology, hospitalization forms, laboratory results of Gomel screening center were entered in the DCC.

Epi Group filled in and entered Initial Abstract Form (demography) and Contact Form.

Table 10 presents the outcome of data entry.

Operational difficulties encountered in accomplishing the task:

Data Coordinating Center

Amount of entered information in the Central Laboratory was limited by one PC. To improve this process additional PC is required.

Milestone 8.4 Conduct routine batch edits of data base

Progress on task:

Data Coordinating Center

Routine batch edits of data base includes the following operations:

- Find duplicates through DB of direct measurements, epidemiology DB and dosimetry interview
- Edit for records of repeated visit within initial type of visit
- Edit for records of initial visit within repeated visit or recall visit for medical reasons
- Edit for antipathy of information concerning passing through examining stations indicated in the control form and records in the DB reflecting examination at these stations for a specified visit.
- Edit for correspondence of nodules number and sizes indicated in the ultrasound examination form and preliminary summary at screening
- Edit for correspondence of nodules number and sizes indicated in the forms of preliminary and final summary
- Edit for missing hospitalization forms in case of referral from the screening center
- Weekly edits for completeness of keyed forms for specified visit.
- Edits for completeness and correctness of records.

Milestone 8.5 Develop tables and reports necessary to monitor study progress

Progress on task:

For the reported period software was updated for automatic generating of tables of quarter progress reports. Tables ## 2, 6, 9 were corrected considering revealed discrepancies for the previous quarter.

Task 9 Develop data management system, and key enter data collected for the study

See the report of dosimetry group.

Task 10 Conduct analyses of data

Preliminary data analysis of TSH estimation in blood serum was conducted.

III. Work Planned for the Next Two Quarters

Task 1 Establish and implement a management plan and quality control procedures for the study

Milestone 1.1 Weekly meetings with the group leaders to discuss the progress of the Project, and their reflection in the minutes.

Milestone 1.2 Administrative support of cohort establishment to supply access to various informational sources, especially sources of address information.

Milestone 1.3. Coordination between Belarus and U.S. participants with respect to all activities of the Project.

Milestone 1.4 Prepare materials for publication in newspapers and radio broadcasting aimed at Project promotion in mass media.

Milestone 1.5 Conduct routine procedures of quality control in Minsk and Gomel examining centers and prepare reports of quality control

Task 3 Trace subjects to determine current address

Milestone 3.2 Develop methods for tracing difficult-to-locate subjects

1-st quarter 2001 – finish locating of subjects through address offices of Minsk and Gomel oblasts. Conduct cross search if financial support will be available.

Work out a strategy for locating subjects moved to another place of residence for follow up examination starting 2-nd quarter 2001.

Milestone 3.3 Trace subjects for current address

1-st quarter 2001 – continue verifying addresses through visiting subjects' places and through local medical stations.

Milestone 3.4 Trace subjects who did not respond to invitation for current address

1-st quarter 2001. – continue verifying addresses through visiting subjects' places and through local medical stations.

Task 4 Enroll and maintain participation of subjects in the study

If financial support will be available, issue informational booklet and send it to the cohort subjects in the middle of 2001.

Task 5 Conduct initial screening examination of subjects

Milestone 5.2 Staff and equip fixed center and mobile screening teams

Milestone 5.4 Send invitation letters to schedule appointments for examination

1-st quarter 2001 – sending informational letters to base line screening examination for completion of cohort enrollment .

Milestone 5.5 Conduct screening examinations

Milestone 5.6 Notify subjects of final screening results

In case of enough expenditures (paper, envelopes) notify subject of screening findings monthly.

Task 6 Conduct second screening of subjects

Milestone 6.1 Review screening process and data collection forms, and revise as necessary

Milestone 6.2 Conduct training sessions for recruiters and interviewers

Conduct training sessions for recruiters and interviewers for the 2-nd cycle of screening.

Milestone 6.3 Send invitation letters to schedule appoints for examination

2-nd quarter 2001 – send invitation letters to schedule appoints for follow up examination in accordance with the plan reflected in the Protocol

Milestone 6.4 Conduct screening examinations

Milestone 6.5 Notify subjects of final screening results

In case of enough expenditures (paper, envelopes) notify subject of screening findings monthly starting the 2-nd .

Task 7 Determine which subjects have developed thyroid cancer or other thyroid diseases

Milestone 7.1 Develop criteria for FNA

It is planned to use FNA criteria developed for the 2-nd screening cycle.

Milestone 7.2 Conduct FNA on appropriate subjects and refer appropriate subjects for surgery

Milestone 7.3 Provide final diagnosis after surgery

Milestone 7.5 Complete laboratory tests for subjects examined

It is planned to complete laboratory tests for examined subjects in accordance with Operations Manual.

Milestone 7.6 Complete final endocrine summary for each subject

Milestone 7.7 Conduct expert reviews of ultrasound findings

Conduct expert review of all new cancer cases, selectively nodular goiter cases and ultrasound thyroid images without pathology.

Milestone 7.8 Conduct expert reviews of cytology for subjects who had FNA

Task 8 Develop data management system, and key enter data collected for the study

Milestone 8.1 Design computer data base to store data

Update and test software for key entry of screening forms in accordance with changes introduced to the forms of data collection for the 2-nd cycle. Install this software in all the Project Units dealing with data entry. Install software in Gomel examining center as soon as equipment will be delivered there.

Milestone 8.2 Develop coding manual and data documentation

To introduce changes to the structure of data in accordance with the changes to the forms of the second cycle. Update coding manual. Work out manual for data management.

Milestone 8.3 Key enter information from data collection forms

Conduct training for operators introducing them changes to software of data entry. Provide data entry with minimal delay.

Milestone 8.4 Conduct routine batch edits of data base

Update software for routine batch edits in accordance with updated structure of data. Conduct routine batch edits of data base on a regular base.

Milestone 8.5 Develop tables and reports necessary to monitor study progress

Update software for generating of tables and reports necessary to monitor study progress in accordance with introduced changes to the DB structure on occasion of 2-nd screening cycle. Update software for generating of quarter reports.

Task 9 The estimation of individual thyroid doses for members of the cohort

Milestone 9.1 Conduct personal interviews for all subjects screened in the Project. Quality control of interview.

Milestone 9.2 Enter to the data base information from the interviews. Quality control of data entry.

Milestone 9.3 Complete estimating reliability of answers for 100 subjects through comparison of the results of initial and repeated interviews.

Milestone 9.4 Continue entering initial dosimetric information to the dosimetry DB.

Milestone 9.5 Work out dosimetry section of Operations

Milestone 9.6 Assess sensitivity of radioecological model for thyroid doses reconstruction in absence of direct measurements.

Table 1. Results of Contacts with Subject for Screening Cycle 1 (Baseline Examination Only)

	Selection I (Record Selected = 19735)			Selection II (Record Selected = 19453)			Total (Record Selected = 39188)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Duplicate Record Found	379		17	141		19	520		36
Total Subjects	19356	100.0	-17	19312	100.0	-19	38668	100.0	-36
Address Found	12841	66.34	-7	10062	52.10	17	22903	59.23	10
Emigrated to Another Country	342	1.77	0	73	0.38	0	415	1.07	0
Deceased	56	0.29	0	40	0.21	0	96	0.25	0
Not Found	6117	31.60	-10	9131	47.28	-36	15248	39.43	-46
Ineligible	0	0.01	0	6	0.02	0	6	0.01	0

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 19735 subjects who were originally selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the end of 1999

Address Found - a current address has been found using at least one of the tracing sources

Not Found - a current address or vital status was unknown by all of the tracing sources

Ineligible - subjects age at time of accident was determined to be out of the range

Table 2. Results of Contacts with Subjects for Screening Cycle 1 (Baseline Screening Examination Only)**

	Selection I (Records Selected = 19735)			Selection II (Records Selected = 19453)			Total (# of Records = 39188)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Address Found	12841		-7	10062		17	22903		10
Invitation Sent	19917		2560	12690		3452	32607		6012
First Invitation	12559	100.0	5	9148	100.0	529	21707	100.0	534
Accepted	3556	28.31	0	2988	32.66	137	6544	30.15	137
Refused	23	0.18	0	17	0.19	0	40	0.18	0
Did Not Respond	7429	59.15	4	5294	57.87	298	12723	58.61	302
Incorrect Address	933	7.43	1	413	4.51	45	1346	6.20	46
Temporarily Absent	497	3.97	0	248	2.71	24	745	3.43	24
Outstanding	0	0.00	0	0	0.00	0	0	0.00	0
Other	121	0.96	0	188	2.06	25	309	1.42	25
Subsequent Invitation	7358	100.00	2555	3542	100.00	2923	10900	100.00	5478
Accepted	1279	17.38	167	419	11.83	119	1698	15.58	286
Refused	17	0.23	9	16	0.45	15	33	0.30	24
Did not respond	5167	70.22	2161	2580	72.84	2506	7747	71.07	4667
Incorrect address	353	4.80	89	196	5.53	101	549	5.04	190
Temporarily Absent	216	2.94	52	64	1.81	59	280	2.57	111
Outstanding	0	0.00	0	0	0.00	0	0	0.00	0
Other	326	4.43	77	267	7.54	123	593	5.44	200

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 19735 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the end of 1999

Temporarily Absent - subject is in the military, prison, school, hospital, or on vacation and is temporarily away from his/her permanent address

Subsequent Invitation - an invitation was previously sent to a subject and they refused, didn't respond, or the address was incorrect; a second or subsequent invitation was sent, possibly with additional information or corrected address (this should be the total number of subjects to whom at least one additional invitation has been sent)

Outstanding - Letter was sent to subject less than one month ago

****** A separate table should be prepared for the second screening examination

Table 2. Results of Contacts with Subjects for Screening Cycle 2

	Selection I (Records Selected = 19735)			Selection II (Records Selected = 19453)			Total (Record Selected = 39188)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Address Found	12841		-7	10062		17	22903		10
Invitation Sent	2261		289	128		26	2389		315
Second Invitation	1551	100.0	84	92	100.0	8	1643	100.0	92
Accepted	621	40.04	12	60	65.22	4	681	41.45	16
Refused	2	0.13	0	0	0.00	0	2	0.12	0
Did Not Respond	828	53.38	58	24	26.09	3	852	51.86	61
Incorrect Address	10	0.64	2	1	1.09	0	11	0.67	2
Temporarily Absent	62	4.00	4	4	4.35	0	66	4.02	4
Outstanding	1	0.06	1	0	0.00	0	1	0.06	1
Other	27	1.74	7	3	3.26	1	30	1.83	8
Subsequent Invitation	710	100.00	205	36	100.00	18	746	100.00	223
Accepted	270	38.03	12	11	30.56	2	281	37.67	14
Refused	0	0.00	0	0	0.00	0	0	0.00	0
Did not Respond	348	49.01	158	17	47.22	13	365	48.93	171
Incorrect Address	13	1.83	2	0	0.00	0	13	1.74	2
Temporarily Absent	14	1.97	4	2	5.56	1	16	2.14	5
Outstanding	0	0.00	0	0	0.00	0	0	0.00	0
Other	65	9.15	29	6	16.67	2	71	9.52	31

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 19735 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the end of 1999

Temporarily Absent - subject is in the military, prison, school, hospital, or on vacation and is temporarily away from his/her permanent address

Subsequent Invitation - an invitation was previously sent to a subject and they refused, didn't respond, or the address was incorrect; a second or subsequent invitation was sent, possibly with additional information or corrected address (this should be the total number of subjects to whom at least one additional invitation has been sent)

Outstanding - Letter was sent to subject less than one month ago

****** A separate table should be prepared for the second screening examination

Table 3. Results of Previous Contact with Subjects Who Were Screened in Screening Cycle I (Baseline Examination Only)

	Selection I (Records Selected = 19735)			Selection II (Records Selected = 19453)			Total (Record Selected = 39188)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Total Who Came to Screening Examination	6599	100.0	330	3793	100.0	642	10392	100.0	972
Accepted Invitation	6092	92.32	105	3087	81.39	262	9179	88.33	367
Refused Invitation	0	0.00	0	0	0.00	0	0	0.00	0
Did Not Respond	318	4.82	163	473	12.47	250	791	7.61	413
Other	177	2.68	62	221	5.83	129	398	3.83	191

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 19735 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the end of 1999

Table 4. Place of Screening for Subjects Who Were Screened in Screening Cycle 1 (Baseline Examination Only)

	Selection I (Records Selected = 19735)			Selection II (Records Selected = 19453)			Total (Record Selected = 39188)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Total Who Came to Screening Examination	6599	100.0	330	3793	100.0	642	10392	100.0	972
Examined at Fixed Center in Minsk	3701	56.08	65	2103	55.44	131	5804	55.85	196
Examined at Fixed Center in Gomel	410	6.21	75	460	12.13	179	870	8.37	254
Examined by Mobile Team	2463	37.32	190	1230	32.43	332	3693	35.54	522
Other	25	0.38	0	0	0.00	0	25*	0.24	0

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 19735 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the end of 1999

* cohort subjects, examined in the dispensary of radiation medicine, but not by the personnel of the Project.

Table 5. Status of Screening Activities for Subjects Who Were Screened in Screening Cycle 1 (Baseline Examination Only)

	Selection I (Records Selected = 19735)			Selection II (Records Selected = 19453)			Total (Record Selected = 39188)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Total Who Came to Screening Examination	6599	100.0	330	3793	100.0	642	10392	100.0	972
Subject had Complete Screening Examination	6504	98.56	324	3743	98.68	642	10247	98.60	966
Subject Missed at Only One Station	64	0.97	4	47	1.24	0	111	1.07	4
Subject Missed Blood Draw Only	13	0.20	1	10	0.26	0	23	0.22	1
Subject Missed Urine Collection Only	28	0.42	1	30	0.79	0	58	0.56	1
Subject Missed Dosimetry Interview Only	23	0.35	2	7	0.18	0	30	0.29	2
Subject Missed Only One Other Station	0	0.00	0	0	0.00	0	0	0.00	0
Subject Missed More than One Station	31	0.47	2	3	0.08	0	34	0.33	2

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 19735 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the end of 1999

Table 6. Preliminary Results of Screening Examination for Subjects Who Were Screened in Screening Cycle 1 (Baseline Examination Only - from the preliminary endocrine summary completed on the day of the examination)

	Selection I (Records Selected = 19735)			Selection II (Records Selected = 19453)			Total (Record Selected = 39188)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Total Who Came to Screening Examination	6599	100.0	330	3793	100.0	642	10392	100.0	972
1. No Thyroid Abnormalities (Follow in 2 Years)	4309	65.30	294	2369	62.46	544	6678	64.26	838
2. Subject Has Single or Multiple Nodules	471	07.14	24	294	07.75	56	765	07.36	80
2.1 At least 1 nodule > 10 mm	177	02.68	8	78	02.06	21	255	02.45	29
2.2 At least 1 nodule > 5 mm but none > 10 mm	261	03.96	14	184	04.85	31	445	04.28	45
2.3 No nodules > 5 mm	33	00.50	2	32	00.84	4	65	00.63	6
3. Parathyroid Dysfunction (Yes or Suspicion)	26	00.39	3	5	00.13	1	31	00.30	4
4. Lymphadenopathy	325	04.92	9	82	02.16	6	407	03.92	15
5. Other Thyroid Abnormality	1669	25.29	0	1024	27.00	0	2693	25.91	0
6. History of Thyroid Surgery Prior to Screening	53	00.80	1	9	00.24	0	62	00.60	1
6.1 Thyroid Cancer	43	00.65	1	4	00.11	0	47	00.45	1
6.2 Thyroid Adenoma	10	00.15	0	5	00.13	0	15	00.14	0
7. Insufficient Information to Complete Preliminary Summary	0	0.00	0	0	0.00	0	0	0.00	0

Definitions:

Selection I - the first 19735 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the end of 1999

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Total Subjects Screened - total number of subjects who came to the first screening examination

History of thyroid cancer prior to screening - subject was diagnosed/treated for thyroid cancer before coming to the first screening examination

Table 7. Fine Needle Aspiration Results from Screening Cycle 1 (Baseline Examination Only)

	Cumulative Total		Change Since Previous Quarter
	#	%	#
Subject requested for FNA	564	100.0	137
Subject was screened at Minsk Fixed Center	317	56.21	59
Subject was screened at Gomel Fixed Center	108	19.15	49
Subject was screened by Minsk Mobile Team	139	24.65	29
Subject was screened by Gomel Mobile Team	0	00.00	0
Subject has NOT undergone FNA	297	52.66	79
Subject was screened at Minsk Fixed Center	138	24.47	26
Subject was screened at Gomel Fixed Center	69	12.23	32
Subject was screened by Minsk Mobile Team	90	15.96	21
Subject was screened by Gomel Mobile Team	0	00.00	0
Subject HAS undergone FNA	267	47.34	58
1 FNA positive or suspicious for cancer	44	07.80	7
2 FNA positive or suspicious for neoplasm	32	05.67	8
3 FNA not suspicious for neoplasm	125	22.16	28
4 Sample(s) Inadequate for Diagnosis	66	11.70	15

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Table 8. *Laboratory Tests Processed*

	Cumulative Total		Change Since Previous Quarter
	#	%	#
1. Blood Samples Received	9881	100.0	683
1.1 Blood Samples Processed for TSH	9331	94.43	651
1.1.1 Blood Samples Processed for Free T4	561	5.68	24
1.2 Blood Samples Processed for anti TPO	9098	92.08	651
1.2.1 Blood Samples Processed for anti Tg	9126	92.36	651
1.3 Blood Samples Processed for Tg	8157	82.55	651
1.4 Blood Samples Processed for Ca++	7847	79.42	651
1.4.1 Blood Samples Processed for PTH	3	0.03	1
2. Urine Samples Received	9745	100.00	913
2.1 Urine Samples Processed	9720	99.74	913

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Samples Received - the number of subjects for whom samples have been received by the laboratory

Samples Processed - the number of subjects for whom each specific laboratory analyses has been completed

Table 9. Final Endocrine Summary Results *

	Selection I			Selection II			Total		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%		#	%		#	%	
Total Subjects Screened	6599		330	3793		642	10392		972
Final Endocrine Summary Report Completed	4460	100.0	103	2099	100.0	156	6559	100.0	259
1. No thyroid abnormality (Follow in 2 years)	2725	61.10	74	1140	54.31	114	3865	58.93	188
2. Thyroid abnormality (ICD-9 Code)	1735	38.90	29	958	45.64	42	2693	41.06	71
2.1 Malignant neoplasm of thyroid gland (193)	38	00.85	3	11	00.52	2	49	00.47	5
2.2 Benign neoplasm of thyroid gland (226)	9	00.20	1	0	00.00	0	9	00.09	1
2.3 Simple and unspecified goiter (240.9)	1188	26.64	4	665	31.68	15	1853	28.25	19
2.4 Nontoxic nodular goiter (241)	254	05.70	7	133	06.34	5	387	05.90	12
2.4.1 Uninodular (241.0)	177	03.97	6	89	04.24	3	266	04.06	9
2.4.2 Multinodular (241.1)	77	01.73	1	44	02.10	2	121	01.84	3
2.5 Thyrotoxicosis with or without goiter (242)	23	00.52	0	23	01.10	2	46	00.70	2
2.5.1 Toxic diffuse goiter (242.0)	1	00.02	0	1	00.05	0	2	00.03	0
2.5.2 Toxic uninodular goiter (242.1)	0	00.00	0	0	00.00	0	0	00.00	0
2.5.3 Toxic multinodular goiter (242.2)	0	00.00	0	0	00.00	0	0	00.00	0
2.5.4 Thyrotoxicosis without goiter (242.4 - 242.9)	22	00.49	0	22	01.05	2	44	00.67	2
2.6 Hypothyroidism (244)	5	00.11	2	3	00.14	0	8	00.12	2
2.7 Other Thyroid Disorders (237.4, 245, 246)	260	05.83	15	139	06.62	22	399	06.08	37
2.7.1 Autoimmune thyroiditis (245.2)	91	02.04	7	43	02.05	13	134	02.04	20
3. Hyperparathyroidism (252.0)	0	00.00	0	0	0.00	0	0	00.00	0
4. Hypercalcemia (275.42)	50	01.12	3	68	03.24	7	118	01.80	10
Subject Has Been Notified of Examination Results	0	0.00	0	0	0.00	0	0	0.00	0

Definitions:

Selection I - the first 19,000 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the end of 1999

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Total Subjects Screened - total of the number of subjects who came to the first screening examination

Final Endocrine Summary/Pathology Completed - the total number of subjects for whom the final endocrine summary report has been completed, and Hospitalization Form (if applicable) and Pathology Form (if applicable) have been completed

* Results from final endocrine summary after all laboratory testing is complete and pathology reports obtained (for subjects with FNA/surgery) - Do not include thyroid abnormalities or malignancies diagnosed prior to the first screening

Table 10. Data Management

	Cumulative Total		Change Since Previous Quarter
	#	%	#
Total Subjects Screened	10392	100.0	972
Screening Forms Key Entered	9948	95.73	960
Dosimetry Questionnaires Key Entered	9313	89.62	645
Urine Processing Forms Key Entered	9808	94.38	920
Blood Processing Forms Key Entered	9483	91.25	650
Final Endocrine Summary Forms Key Entered	6248	60.12	213
FNA Results Forms Key Entered	380	3.66	43
Pathology Forms Key Entered	0	0.00	0
Initial Abstract Forms Key Entered	23943		1290
Hospital Clinic Forms Key Entered	485		38
Hospital Oncopathology Forms Key Entered	109		10

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Current Quarter - total number for this quarter beginning and ending with the dates on the front page of this report

Total Subjects Screened - total of the numbers of subjects screened in Screening Cycle 1

Screening Forms Key Entered - total number of subjects for whom all forms filled out on the day of screening (from registration through preliminary endocrine summary) have been key-entered